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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL NO. 1456 CIVIL ACTION NO. 01-CV-12257-PBS Hon. Patti B. Saris
THIS DOCUMENT RELATES TO ALL ACTIONS	

ASTRAZENECA PHARMACEUTICALS LP'S MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT

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Preliminary Statement

Defendant AstraZeneca Pharmaceuticals LP ("AstraZeneca") respectfully submits this memorandum of law in support of its motion for summary judgment pursuant to Rule 56 of the Federal Rules of Civil Procedure. As set forth below, summary judgment is appropriate on several independent grounds: the Class 1 plaintiffs' failure to show the impropriety and inaccuracy of the federal agency's determinations of the amounts required to be paid for Medicare Part B drugs, which are binding under federal law (Point I); Class 1 plaintiffs Robert Howe's and Leroy Townsend's failure to present any genuine issue of material fact on necessary elements of claims for relief under the governing state consumer protection statutes of Oregon and Florida (Points II and III); and the absence of any proof supporting the Class 1 and Class 2 claims relating to Pulmicort Respules (Point IV). In addition, there are several other grounds on which summary judgment or partial summary judgment should be granted to AstraZeneca, set forth in the Joint Submission of the Track 1 defendants being filed simultaneously herewith. The bases for summary judgment are the testimony of the class plaintiffs and the absence of evidence supporting necessary elements of plaintiffs' claims, based on the standard set forth by the Supreme Court in *Celotex Corp. v. Catrett*, 477 U.S. 317, 325 (1986). *See First Marblehead Corp. v. House*, 401 F. Supp. 2d 152, 156 (D. Mass. 2005) (Saris, J.).

I. Class 1 Plaintiffs Have Not Established CMS' Determinations Are Wrong, and Federal Law Binds Class 1 Plaintiffs to CMS' Determinations

As detailed below, Mr. Townsend and Mr. Howe were treated for prostate cancer by their doctors with injections of AstraZeneca's drug Zoladex; their doctors submitted requests for payment to Centers for Medicare & Medicaid Services ("CMS," formerly Health Care Financing Administration, or "HCFA"). CMS was required by statute to determine the amounts federal law

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required to be paid under Medicaid Part B, *see* 42 U.S.C. § 1395u, and to provide an Explanation of Medicare Benefits ("EOMB") that, *inter alia*, set out the appropriate amounts of payment for physicians' services. 42 U.S.C. § 1395b(7)(a)(1). CMS regulations specified the methodology used to determine the appropriate price for a Medicare Part B drug or biological. 42 U.S.C. § 405.517(b) (formerly § 405.517). The EOMBs set forth CMS' determinations of the appropriate amounts required by federal law to be paid by Medicare Part B and the separate co-pay amounts their doctors could bill Mr. Townsend and Mr. Howe.

Neither Mr. Townsend nor Mr. Howe disputed, requested redetermination, or appealed the CMS determinations. *See* 42 C.F.R. § 405.801 (repealed 2005); Tab 1, 56.1 Statement ¶¶ 13, 14 (Deposition of Robert A. Howe ("Howe Dep.") at 100, 134); Tab 2, 56.1 Statement ¶ 35 (Deposition of Leroy Townsend ("Townsend Dep.") at 173-74.)[1] As neither questioned, disputed, nor protested the propriety or accuracy of these amounts determined by CMS to be required under Medicare Part B, the accuracy and propriety of those amounts set forth on Mr. Townsend's and Mr. Howe's EOMBs are, as a matter of federal law, binding. 42 C.F.R. § 405.806.

CMS is the federal administrative agency charged with the administration of Medicare Part B, including determining the amounts that are required by the federal Medicare Part B plan to be paid for Medicare Part B drugs, including Zoladex. Neither Mr. Townsend nor Mr. Howe has established in the record that the amounts determined by CMS were not the appropriate Medicare and patient co-pay amounts that federal law required to be paid for these physician

[1] Note that both Mr. Howe and Mr. Townsend failed to dispute charges for their Zoladex treatments even though Mr. Townsend had filed complaints in Illinois and Delaware alleging pricing misrepresentations, and Mr. Howe testified that he was aware of the lawsuit in 2001. *See infra* pp. 9-10.

requests for payments for Zoladex. Mr. Townsend and Mr. Howe are bound, as a matter of federal law, by CMS' determinations that the amounts on the EOMBs are the proper and accurate amounts required to be paid by Medicare Part B and as co-payments to doctors for injections of Zoladex. By application of the Supremacy Clause, no state law can be invoked or utilized to purport to determine that amounts different from those determined by the federal agency administering the federal law should have been paid under federal law. Similarly, no state law can purport to annul federal law that the CMS determinations of the Medicare Part B co-pay amounts are now binding. As such, AstraZeneca is entitled to summary judgment on the claims of Class 1 plaintiffs Mr. Townsend and Mr. Howe and their Class 2 MediGap insurers with respect to Zoladex.

II. Summary Judgment Is Required on the Claim of Class Representative Robert A. Howe Under Oregon UTPA[2]

A. The Pertinent Factual Record of Mr. Robert A. Howe

Robert Howe of Oregon, a named class representative of the class asserting claims against AstraZeneca, was diagnosed with prostate cancer,

Tab 1, 56.1 Statement ¶¶ 6, 9, 11 (Howe Dep. at 81, 207).

Tab 1, 56.1 Statement ¶ 12 (*id.* at 124).

(Tab 1, 56.1 Statement ¶ 15 (*id.* at 125)), and that medical providers should not be obligated to tell a patient what they pay for a drug, Tab 1, 56.1 Statement ¶ 16 (*id.* at 132.)

[2] The Oregon Unfair Trade Practices Act applies herein as the Court's Class Certification Order names Oregon as one of the 44 states applicable to Class 1. (*See* Consolidated Order Re: Motion for Class Certification ¶ 4, Jan. 30, 2006.)

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Tab 1, 56.1 Statement ¶ 15 (*id.* at 134, 137). Mr. Howe never discussed the price of Zoladex with any of his doctors, nor did he attempt to negotiate the price of his treatments or discuss potential alternative, less costly treatments with any of his physicians. Tab 1, 56.1 Statement ¶ 13 (*id.* at 134.)

and physicians should not be obligated to disclose drug costs to patients. Tab 1, 56.1 Statement ¶¶ 15, 16 (*id.* at 132.) He had no knowledge as to how medical providers determine their charges for medications, nor did he have any knowledge as to how drug prices are determined by manufacturers. Tab 1, 56.1 Statement ¶ 18 (*id.* at 86-87.) Mr. Howe never had knowledge of the AWP of any of the drugs he was taking at any time, nor had Mr. Howe heard of any of the publications within which AWP is published. Tab 1, 56.1 Statement ¶¶ 20, 21 (*id.* at 90, 93-94.) There is no evidence that Mr. Howe relied on any statement concerning AWP.

Mr. Howe, a Medicare Part B recipient, also had supplemental insurance coverage provided by his former employees through United HealthCare, which covers the 20 percent co-pay. Tab 1, 56.1 Statement ¶ 8 (*id.* at 61, 66.) Upon receiving treatment, Mr. Howe would present his doctor with a Medicare form and his United HealthCare card and his doctor's office would bill both Medicare and his supplemental insurance company. Tab 1, 56.1 Statement ¶ 22 (*id.* at 67.)

In addition to regularly receiving EOMBs in the mail, Mr. Howe testified that he read those forms. Tab 1, 56.1 Statement ¶ 23 (*id.* at 52-53). Mr. Howe made sure to save the forms for later reference. Tab 1, 56.1 Statement ¶ 23 (*id.* at 54). Although he received and read those

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forms, Mr. Howe admitted that he never attempted to contact Medicare to raise any concerns. Tab 1, 56.1 Statement ¶ 14 (*id.* at 100).

Mr. Howe produced some copies of EOMBs reflecting certain administrations of Zoladex, (Tab 16, 56.1 Statement ¶ 24 (HOWE 0014-25)), and some cancelled checks, Tab 15, 56.1 Statement ¶ 24 (HOWE 0001-13.) However, the cancelled checks do not correspond to the EOMBs in a manner that reflects how much or on what basis Mr. Howe allegedly paid for Zoladex. Mr. Howe testified that he did not pay his doctors based upon the co-pay amounts on the EOMBs, but upon bills sent by his doctor's office; therefore, the amounts of his checks do not correspond to the co-pay amounts of the EOMBs. Tab 1, 56.1 Statement ¶ 17 (Howe Dep. at 184.) Mr. Howe testified that he would not be able to match particular cancelled checks to particular medical services his doctor provided because the doctor bills he received did not specify the services for which he was billed. Tab 1, 56.1 Statement ¶ 17 (*id.* at 192.)[3]

Mr. Howe testified he had no knowledge as to how medical providers determine their charges for medications, nor did he have any knowledge as to how drug prices are determined by manufacturers. Tab 1, 56.1 Statement ¶ 18 (*id.* at 86-87.) Mr. Howe first learned of the term "average wholesale price" from his lawyer in 2005, (Tab 1, 56.1 Statement ¶ 19 (*id.* at 88-89)), and never had knowledge of the AWP of any of the drugs he was taking at any time. Tab 1, 56.1 Statement ¶ 20 (Howe Dep. at 90.) Mr. Howe had never heard of any of the publications within which AWP is published. Tab 1, 56.1 Statement ¶ 21 (*id.* at 93-94.)

[3] Although counsel for Mr. Howe attempted to decode the billing statements provided by Mr. Howe's physician to show payments for Zoladex injections, these lawyer affidavits are not admissible evidence and fail to prove that Mr. Howe's payments were based upon AWP. (*See* Haviland Decl. in Supp. of Pls.' Mem. in Supp. of Proposed Consolidated Class Certification Order, ¶¶ 40-42, Dec. 13, 2005.)

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B. There Is No Evidence of Violation of Necessary Elements of Oregon UTPA

1. There Is No Violation of Oregon UTPA

To prove a claim under the Oregon Unfair Trade Practices Act ("UTPA"), codified at ORS. 646.605 *et seq.*, a plaintiff must prove, as a threshold matter, that the defendant has violated one of the 56 enumerated unlawful practices codified at ORS 646.608(1)(a)-(bbb).[4] *Feitler v. Animation Celection, Inc.*, 170 Or. App. 702, 708 (2000). The allegations of the present class complaint—with respect to publishing "inflated" AWP—do not fit any of the 56 practices covered by UTPA, and there is no evidence in the record that AstraZeneca committed any acts that would meet the requirements of any subdivision of UTPA. (*See* Fourth Amended Master Consolidated Class Action Complaint ("FAMCC"), *passim*.) Although the residuary clause of the statute, ORS 646.608(u), makes it unlawful for a person to "[e]ngage[] in any other unfair or deceptive conduct in trade or commerce," this catch-all subsection is qualified by ORS 646.608(4), which provides that, "[n]o action or suit shall be brought under subsection (1)(u) of this section unless the Attorney General has first established a rule in accordance with the provisions of ORS chapter 183 declaring the conduct to be unfair or deceptive in trade or commerce." *See also Sanders v. Francis*, 277 Or. 593, 595-96 (1977) (reiterating that ORS 646.608(1)(u) must be further specified by the Attorney General through rulemaking procedures). The conduct alleged in the class complaint is not actionable under the residuary

[4] Examples of enumerated unlawful practices included in the statute are instances where a person: "(a) Passes off real estate, goods or services as those of another; (b) Causes likelihood of confusion or of misunderstanding as to the source, sponsorship, approval, or certification of real estate, goods or services; (c) Causes likelihood of confusion or of misunderstanding, as to affiliation, connection, or association with, or certification by, another; (d) uses deceptive representations or designations of geographic origin in connection with real estate, goods or services . . . ." ORS 646.608(1)(a)-(d).

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clause, as there is no evidence in the record that conduct by AstraZeneca (whether as alleged in the complaint or otherwise) violated any rule previously established by the Oregon Attorney General as required by Oregon law.

2. There is No Evidence of "Willful" Violation of UTPA

Evidence of a facial violation of one of the 56 specific paragraphs of the UTPA, while necessary, is not sufficient to sustain a claim under that Act. Mr. Howe must also prove that AstraZeneca "willfully" violated the UTPA. "A private party who seeks to recover damages for a UTPA violation must plead and prove a 'willful' violation of the statute by the defendant. 'A willful violation occurs when the person committing the violation knew or should have known that the conduct of the person was a violation.'" *Rathgeber v. James Hemenway, Inc.*, 335 Or. 404, 413 (2003) (quoting ORS 646.605(10)). There is no evidence in the record that AstraZeneca actually knew the alleged conduct violated UTPA, and no evidence upon which to conclude AstraZeneca should have known its conduct violated UTPA.

3. There is No Evidence that Mr. Howe Relied

UTPA also requires a plaintiff to prove causation. *Feitler v. Animation Celection, Inc.*, 170 Or. App. 702, 708 (2000). Mr. Howe must offer evidence that he suffered a loss "as a result of" AstraZeneca's conduct. *Id.*; 170 Or. App. 702, 708 (2000). Reliance is treated as an element of causation. *See Pearson v. Philip Morris, Inc.*, No. 0211-11819, 2005 WL 2840670, at *5 (Or. Cir. Oct. 12, 2005); *Sanders v, Francis,* 277 Or. 593, 598 (1977) ("In many cases plaintiff's reliance may indeed be a requisite cause of any loss, i.e. when plaintiff claims to have acted upon seller's express representations."). Thus, "[w]hether ORS 646.608(1) requires reliance as an element of causation necessarily depends on the particular unlawful practice alleged." *Sanders,* 277 Or. 593 at 598.

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The facts of Mr. Howe's claim are analogous to the allegations made by plaintiffs in *Pearson v. Philip Morris, Inc.*, where the Oregon court required a showing of reliance for plaintiffs to maintain their cause of action under the UTPA.[5] That case involved a motion to certify a class consisting of all Marlboro Lights purchasers asserting that the label "Light Cigarettes" was misleading and deceptive. The court held that because, in essence, plaintiffs claimed that assertions about the product were false ("Lights" were not "light"), each member of the proposed class had to prove that the false statement was a substantial factor in his or her decision to purchase each pack of Marlboro Lights for which recovery was sought. *Pearson*, 2005 WL 2840670, at *5. The court found a reliance requirement because it viewed the claim as one of misrepresentation and therefore, plaintiffs had to show that they had relied on defendant's misrepresentation for their claim to proceed.

Similarly, Mr. Howe alleges that because AstraZeneca reported inflated AWPs to trade publications, he was overcharged for his treatments. (*See* FAMCC ¶ 250.) Similar to *Pearson*, Mr. Howe's argument, for purposes of the Oregon UTPA, essentially charges that defendant's reported assertions were affirmative misrepresentations of average wholesale price ("published AWP" was not the "actual AWP"). Under the Oregon case law, such misrepresentation claims require a showing that Mr. Howe relied on AstraZeneca's alleged misrepresentations of the meaning of AWP and that reliance caused him to overpay.

There is no evidence in the record that Mr. Howe relied on any representations about AWP or otherwise, made by AstraZeneca or anyone, in pursuing his course of treatment with

[5] ORS 646.608(2) provides, "[a] representation under subsection (1) of this section or ORS 646.607 may be any manifestation of any assertion by words or conduct, including, but not limited to, a failure to disclose a fact."

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Zoladex. Moreover, the use of Zoladex was not related in any way to the price of the drug, or any price claims made by either the drug manufacturer or his physician. *See supra* p. 4.

4. Robert A. Howe Is Charged With Knowledge

That complaint includes allegations that Medicare Part B beneficiaries were overpaying for treatments. (*See Citizens for Consumer Justice, et al. v. Abbott Labs., Inc., et al.*, Case No. 01 CV 12257 (D. Mass. Dec. 19, 2002) ("Massachusetts Complaint") ¶¶ 74, 96 (noting that at least as early as 1997, the DOJ, GAO, and OIG were "investigating [defendants] for questionable practices regarding the industry's calculation of the AWP and offering illegal incentives to health care providers" and alleging that defendants posted "artificially inflated prices" in industry publications upon which plaintiffs relied to their detriment).) Further, Mr. Howe testified that he first learned about the present lawsuit in either 2000 or 2001. Tab 1, 56.1 Statement ¶ 10 (Howe Dep. 17.) Moreover, in his deposition Mr. Howe stated that he participated in a lawsuit relating to Lupron in 2001. Tab 1, 56.1 Statement ¶ 10 (*id.* at 17-22.)

the alleged pricing methods concerning AWP were publicly known. As such, when Mr. Howe allegedly began paying for Zoladex injections, he was charged with full knowledge of the meaning of AWP and the alleged conduct. *See McCabe v. Kelleher*, 90 Or. 45, 53 (1918) (stating that it is the general rule that a purchaser must make use of his means of knowledge, and failing to do so, he cannot recover on the ground that he was misled by

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a seller). Plaintiff nonetheless claims to have continued to pay for his Zoladex treatments. Mr. Howe never complained about the price of his treatments, refused to pay, or paid under protest. Tab 1, 56.1 Statement ¶¶ 13, 14 (Howe Dep. at 100, 134.) As such, any injury to Mr. Howe was "by reason of" his own inaction.

III. Summary Judgment Is Required on the Claim of Class Representative Leroy Townsend Under Florida DUTPA

A. The Pertinent Factual Record of Mr. Leroy Townsend

Leroy Townsend is alleged to be "a Medicare recipient who took Zoladex and paid a 20% co-payment." (FAMCC ¶ 14.) On June 12, 2001, he filed a class action complaint regarding the pricing of Lupron in Illinois. Tab 3, 56.1 Statement ¶ 29 (*Townsend v. TAP Pharmaceutical Prods., Inc.*, No. 1:01-CV-04435, (N.D. Ill. June 12, 2001) ("Illinois Complaint").) Further, on January 16, 2002, he filed a class action against AstraZeneca in the U.S. District Court for the District of Delaware, which has been consolidated into the FAMCC. Tab 17, 56.1 Statement ¶ 28 (*Townsend v. AstraZeneca, PLC*, No. 02-046 (D. Del. Jan. 16, 2002) ("Delaware Complaint").)

Mr. Townsend testified that he enrolled in Medicare in February of 1985, (Tab 2, 56.1 Statement ¶ 30 (Townsend Dep. at 15)),

Tab 2, 56.1 Statement ¶ 31 (*id.* at 60-62.) Mr. Townsend allegedly made co-payments for Zoladex injections on six occasions, in 1999, 2000 (thrice), 2001, and 2002 in the amounts listed on his EOMBs as what his doctor could bill him. Tab 4, 56.1 Statement ¶ 37 (TOWN 001-02 (cancelled checks)); Tab 5, 56.1 Statement ¶ 36 (TOWN 500-503 (patient financial history)); Tab 6, 56.1 Statement ¶ 37 (TOWN 0058; TOWN 0223; TOWN 0060; TOWN 0317-23 (EOMBs).). Mr. Townsend used the billing information on the EOMBs, adding that it was

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"Medicare's determination" how much he would be charged for Zoladex. Tab 2, 56.1 Statement ¶ 32 (Townsend Dep. at 79, 80-81.)

Mr. Townsend also had supplemental insurance coverage provided by the successor bank to his former employer; he was first covered by Aetna, and then by United HealthCare (from roughly 1999 or 2000). Tab 2, 56.1 Statement ¶ 33 (*id.* at 25-27.) Mr. Townsend could not explain why he would be making co-insurance payments for his Zoladex injections while he had supplemental insurance. Tab 2, 56.1 Statement ¶ 33 (*see id.* at 37-38 (noting that for services covered by United HealthCare he had no out-of-pocket expenses); *id.* at 124-26 (noting that Aetna did not always provide coverage); *id.* at 137-38 (noting he had no idea why he would be personally responsible for co-payments for Zoladex).)

In fact, I didn't know about it until I got the form from Medicare advising me each quarter what it was, and then I saw that, and I don't think I even asked him about it at the time." Tab 2, 56.1 Statement ¶ 36 (*id.* at 71.) Mr. Townsend "never" discussed drug prices with his doctor: "I never asked him right from the get-go. I never questioned the price. I was happy to be doing whatever was necessary to be done, ..." Tab 2, 56.1 Statement ¶ 36 (*id.* at 72); *see also* (*id.* at 81 ("[T]he price is what it is. If you want it, you pay for it. If you don't want it, you don't pay.")); (*id.* at 81-82 (testifying that he never negotiated with his doctor over price)).

Tab 2, 56.1

Statement ¶ 38 (*id.* at 75); *see also* (*id.* at 77-78

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Prior to his involvement in this lawsuit, Mr. Townsend had never heard of either "average wholesale price" or "AWP," nor had he ever seen it referenced in Red Book or any other publication. Tab 2, 56.1 Statement ¶ 34 (*id.* at 57, 59.) Notably, this testimony directly contradicts the allegations Mr. Townsend made in the Delaware Complaint that AstraZeneca deliberately inflated the AWP of its drugs. Tab 17, 56.1 Statement ¶ 28 (Del. Compl. ¶ 4; *see also* Tab 3, 56.1 Statement ¶ 29 ((Ill. Compl. ¶¶ 31, 38) (referencing Red Book and alleging that defendant in that action "artificially inflated AWP").) Mr. Townsend has no understanding of how AWP is calculated or how the payments he allegedly made for Zoladex related to AWP. Tab 2, 56.1 Statement ¶¶ 34 (Townsend Dep. at 57, 81.) He testified that his doctor did not have any obligation to disclose any difference between the amount paid for a drug and the amount charged, stating, "I don't know why he would have an obligation to tell me about anything. I mean, as I've indicated before, I had enough confidence in him that whatever he did for me and whatever he billed me for, that was his problem, not mine." Tab 2, 56.1 Statement ¶ 36 (*id.* at 85.)

Even after he filed a class action complaint against AstraZeneca in January of 2002, alleging that AstraZeneca "artificially inflated the AWP" of Zoladex, (Tab 17, 56.1 Statement ¶ 28 (Del. Compl. ¶ 41(b)), and prepared "marketing and sales materials which contained comparisons of the *Red Book* AWP and the actual average wholesale price," (Tab 17, 56.1 Statement ¶ 28 (*id.* ¶ 41(c)), Mr. Townsend did not raise the issue of drug prices with his doctor. Tab 2, 56.1 Statement ¶ 36 (Townsend Dep. at 173-74.) Indeed, he alleges that he made an out-of-pocket co-payment for Zoladex shortly *after* filing his complaint in or around March or April 2002, without any complaint or protest. Tab 4, 56.1 Statement ¶ 37 (TOWN 0002 (Apr. 1, 2002)); Tab 5, 56.1 Statement ¶ 37 (TOWN 0501.) He did not challenge any of the

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determinations that CMS made and listed on the EOMB of the co-pay amount his doctor could charge him for Zoladex injections that he was obligated to pay. Tab 2, 56.1 Statement ¶ 35 (Townsend Dep. at 173-74.)

B. Florida's Deceptive and Unfair Trade Practices Act[6]

Florida's Deceptive and Unfair Trade Practices Act ("FDUTPA"), §§ 501.201-501.213 (2005), is "directed to entities that have traditionally been thought of as consumers, in situations traditionally thought of as consumer transactions." *Monsanto Co. v. Campuzano*, 206 F. Supp. 2d 1252, 1269 (S.D. Fla. 2002). To establish a claim under FDUTPA, a plaintiff must prove that as a "consumer," the plaintiff suffered actual damages that were proximately caused by defendant's deceptive conduct in the course of trade or commerce. *See Losure v. Capital One Servs.*, No. 2:05CV502FTM29SPC, 2006 WL 166520, at *3 (M.D. Fla. Jan. 23, 2006); *Merrill Lynch Bus. Fin. Servs., Inc. v. Performance Machine Sys. U.S.A., Inc.*, No. 04-60861-Civ., 2005 WL 975773, at *8 (S.D. Fla. Mar. 4, 2005).

1. AstraZeneca Is Entitled to Summary Judgment on the FDUTPA Claim Relating to Zoladex

There is no evidence in the record establishing that AstraZeneca's conduct was either deceptive or that AstraZeneca proximately caused Mr. Townsend to suffer ascertainable loss, entitling AstraZeneca to summary judgment.

[6] The Florida Deceptive and Unfair Trade Practices Act is applicable herein as the Judge's Class Certification Order names Florida as one of the 44 states applicable to Class 1. (*See* Consolidated Order Re: Motion For Class Certification ¶ 4, Jan. 30, 2006.)

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a. There is No Evidence in the Record that AstraZeneca's Conduct Was Deceptive Under Florida Law

Incorporating the Federal Trade Commission standard for deception, Florida courts have stated that "deception" will be found if there is a "'representation, omission or practice that is likely to mislead the consumer acting reasonably in the circumstances, to the consumer's detriment.'" *Millennium Commc'ns & Fulfillment, Inc. v. Office of the Attorney General*, 761 So.2d 1256, 1263 (Fla. Ct. App. 3d Dist. 2000) (quoting *Sw. Sunsites, Inc. v. FTC*, 785 F.2d 1431 (9th Cir. 1986)); *accord PNR, Inc. v. Beacon Property Mgmt., Inc.*, 842 So.2d 773, 777 (Fla. 2003). Notably, this represents a heightened showing from what was previously contemplated under the law, as explained by the Ninth Circuit in the *Southwest Sunsites* case:

> First, the [claimant] must show probable, not possible, deception ('likely to mislead,' not 'tendency and capacity to mislead'). Second, the [claimant] must show potential deception of 'consumers acting reasonably in the circumstances not just any consumers.' Third, the new standard considers as material only deceptions that are likely to cause injury to a reasonable relying consumer, whereas the old standard reached deceptions that a consumer might have considered important, whether or not there was reliance.

785 F.2d at 1436; *see also Millennium Commcn's & Fulfillment, Inc.*, 761 So.2d at 1263. Significantly, "[m]ateriality," under FTC case law, to which the FDUTPA ascribes "great weight," Fla. Stat. § 501.204(2), is defined as a "representation or practice [that] is likely to affect a consumer's choice of or conduct regarding a product. In other words, it is information that is important to consumers. If inaccurate or omitted information is material, injury is likely." *In re Cliffdale Assocs.*, 103 F.T.C. 110, 1984 FTC LEXIS 71, at *107 (FTC 1984).

The FDUTPA covers a representation, practice, or omission that is likely to mislead a consumer acting reasonably, to the consumer's detriment. There must be either an express or implied claim that is not met or material information that is not disclosed that the plaintiff can

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readily identify as forming the basis of the "deceptive" conduct. *See, e.g., Millennium Commc'ns & Fulfillment, Inc.*, 761 So.2d at 1263-1264 (postcard mailed to consumers pointed to as likely to mislead readers into believing they were eligible to receive Visa or MasterCard credit cards) (finding no deception); *Fendrich v. RBF, L.L.C.*, 842 So.2d 1076, 1077 (Fla. Ct. App. 4th Dist. 2003) (reservation form identified as likely to mislead recipient into believing he would receive a superior lot for a lower price than he was offered) (finding deception sufficiently pleaded).

There is no evidence in the record of an express or implied claim made by AstraZeneca that was likely to mislead or deceive, or any evidence that Mr. Townsend himself was "deceived" or misled into allegedly overpaying for Zoladex.

he did not ask about or have concern about the cost of the drugs used to treat his cancer. There is no evidence that the price of the drugs used to treat the prostate cancer was important to Mr. Townsend. *See supra* pp. 10-11. CMS determined what co-pay was required for Zoladex and Mr. Townsend alleges he paid his doctor accordingly.

b. There is No Evidence in the Record that AstraZeneca's Conduct Proximately Caused Mr. Townsend's Alleged Loss

It is well established under Florida law that a plaintiff seeking damages under FDUTPA "must show not only that a defendant engaged in unfair or deceptive trade practices but also that those practices caused injury to the plaintiff." *Chicken Unlimited, Inc. v. Bockover*, 374 So.2d 96, 97 (Fla. Ct. App. 2d Dist. 1979) (reversing court's judgment in favor of plaintiff, on the ground that there was sufficient evidence that the plaintiff knew of the possible falsity of defendant's statements); *see also* Fla. Stat. § 501.211(2) ("In any action brought by a person who

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has *suffered a loss as a result of a violation of this part*, such person may recover actual damages . . . .") (emphasis added); *Macias v. HBC of Fla., Inc.*, 694 So.2d 88, 90 (Fla. Ct. App. 3d Dist. 1997) ("[F]or the consumer to be entitled to any relief under FDUTPA, the consumer must not only plead and prove that the conduct complained of was unfair and deceptive but the consumer must also plead and prove that he or she was aggrieved by the unfair and deceptive act.") (affirming dismissal of complaint on ground that speculative losses are not recoverable under FDUTPA). "Subjective feelings of disappointment are insufficient to form a basis of actual damages." *Id.* Put differently, "to prove liability under FDUTPA, the Court must determine that (1) each . . . class member was exposed to Defendants' advertising and marketing materials alleged to constitute a deceptive trade practice and (2) if exposed, the advertising and marketing materials caused each . . . class member damage." *Montgomery v. New Piper Aircraft, Inc.*, 209 F.R.D. 221, 229 (S.D. Fla. 2002); *see also Philip Morris USA Inc. v. Hines*, 883 So.2d 292, 294-95 (Fla. Ct. App. 4th Dist. 2003).

Mr. Townsend cannot demonstrate that AstraZeneca's allegedly deceptive conduct proximately caused him to make "overpayments" for Zoladex. Simply stated, Mr. Townsend received from CMS a notice stating the co-pay amount he could be billed by his doctor under Medicare Part B; he allegedly paid his doctor. All that happened here was Mr. Townsend allegedly paid an amount of money—the 20% Medicare Part B co-pay—for a medication prescribed by his provider, which amount was determined to be required by Medicare Part B by the federal agency charged with administering the law in conformity with federal law and regulations. Under Florida law, Mr. Townsend has not presented evidence that the loss he allegedly suffered—payment of the co-pay to his doctor—was proximately caused by AstraZeneca.

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2. The Statute of Limitations Operates to Preclude Any Claims Under FDUTPA Prior to 1997

The statute of limitations for any statutory violation under Florida law, including claims brought pursuant to the FDUTPA, is four years. *See* Fla. Stat. § 95.11(3)(f). Section 95.051 specifically enumerates eight grounds for tolling statutes of limitations under Florida law, § 95.051(1), and further provides that "[n]o disability or other reasons shall toll the running of any statute of limitations except those specified in this section, the Florida Probate Code, or the Florida Guardianship Law," § 95.051(2). This statute has been strictly construed. For instance, one court noted:

> As the Florida Supreme Court has recently reiterated, "when construing statutes of limitations, courts generally will not write in exceptions when the legislature has not." [*Fed. Ins. Co. v. Sw. Fla. Ret. Ctr., Inc.*, 707 So.2d 1119, 1122 (Fla. 1998).] Because fraudulent concealment is not included among the tolling provisions recognized in § 95.051 and because this Court has found that § 95.051 has not been overturned, [plaintiffs'] damages under their FDUTPA claims are limited to those accruing within the four-year limitations period.

In re: Vitamins Antitrust Litig., No. Misc. 99-197 TFH, 2000 WL 33975412, at *5 (D.D.C. Oct. 26, 2000) (rejecting fraudulent concealment argument and limiting FDUTPA claims to four-year period); *accord Senger Bros. Nursery, Inc. v. E.I. DuPont de Nemours & Co.*, 184 F.R.D. 674, 684 (M.D. Fla. 1999).

The first of the class action complaints was filed on December 19, 2001, *see* Massachusetts Complaint, and the first consolidated complaint—the Master Consolidated Class Action Complaint –was filed on September 6, 2002, *see In re: Pharm. Indus. Average Wholesale Price Litig.*, No. 01-CV-12257 (PBS) (D. Mass. Sept. 6, 2002). A cause of action accrues when the last element of the cause of action occurs. *See Davis v. Monahan*, 832 So.2d 708, 709 (Fla. 2002). Notably, the original Massachusetts Complaint contained allegations

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clearly setting forth the "deceptive" behavior. (*See* Mass. Compl. ¶¶ 74, 96 (noting that at least as early as 1997, the DOJ, GAO, and OIG were "investigating [defendants] for questionable practices regarding the industry's calculation of the AWP and offering illegal incentives to health care providers" and alleging that defendants posted "artificially inflated prices" in industry publications).)

In this case, a supposed new cause of action under FDUTPA would accrue each time a Medicare Part B co-payment for Zoladex was made. Accordingly, the claims of Mr. Townsend (and every other person) under FDUTPA based on alleged co-payments for Zoladex made prior to September 6, 1998 are likely barred—and co-payments made prior to December 19, 1997 are unquestionably barred—by the applicable statutes of limitations.[7]

IV. Summary Judgment is Required on the Claims of Class 1 and Class 2 with Respect to Pulmicort Respules

There is no evidence in the record supporting the Class 1 and Class 2 claims relating to Pulmicort Respules.

Plaintiffs allege that plaintiffs and members of the class paid for the drugs based on the inflated AWPs reported by defendants. (FAMCC ¶¶ 152, 175.) There is no evidence in the record that any of the class representatives for Class 1 made any payments at all for Pulmicort Respules under Medicare Part B. Only two Class 1 representatives are certified for AstraZeneca: Mr. Townsend and Mr. Howe. Mr. Townsend testified that he never heard of, let alone used or

[7] The most recent amended class complaint purports to assert claims based on co-payments made through 2005. The initial class action complaint was filed on December 19, 2001, and the Master Consolidated Class Action Complaint was filed on September 6, 2002, publicly trumpeting the supposed fraud and deception. Any co-payments made by any class member thereafter, especially made without complaint or protest, are precluded on numerous grounds of state and federal law. Indeed, Mr. Townsend allegedly made a co-payment for Zoladex to his doctor without complaint or protest in the amount CMS determined after Mr. Townsend himself filed the class action complaint. See p.10, *supra*.

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purchased Pulmicort Respules. Tab 2, 56.1 Statement ¶ 39 (Townsend Dep. at 60.) Similarly, there is likewise no evidence in the record that Mr. Howe ever took or paid for Pulmicort Respules. Thus, there is no member of Class 1 before this Court that establish a claim against AstraZeneca by presenting specific facts relating to alleged over-payments made for Pulmicort Respules under Medicare Part B. Accordingly, summary judgment should be granted to AstraZeneca with respect to any Class 1 claims relating to Pulmicort Respules.

Even if the Class 1 claims relating to Pulmicort Respules could be maintained in the absence of evidence of any specific purchases, which they cannot, there is no evidence in the record to support plaintiffs' allegation that the AWP for Pulmicort Respules was inflated. Plaintiffs allege in the Complaint that AWPs for the drugs at issue bore little relationship to the drugs' pricing in the marketplace (FAMCC ¶ 151) and that defendants deliberately published AWPs for the drugs at issue that did not reflect the actual pricing structure of the drugs (*id.* at ¶ 174.) In fact, it is undisputed that the vast majority of Pulmicort Respules sales to non-governmental customers were made at or close to the published list price, or WAC, for Pulmicort Respules and that the published AWP for Pulmicort Respules was consistently 20% to 25% above WAC. (Direct Sales Data, AZ0466414); Tab 10, 56.1 Statement ¶ 52 (Declaration of Zahir Ladhani "Ladhani Decl." at ¶ 11.) Even plaintiffs' expert concedes that there is no liability under plaintiffs' theory of the case for Pulmicort Respules, because the "spread" between Dr. Hartman's calculation of the Average Sales Price ("ASP") for Pulmicort Respules and the published AWP for Pulmicort Respules has at all times been less than Dr. Hartman's "liability yardstick" of 30%. Tab 7 (Deposition of Dr. Raymond S. Hartman ("Hartman Dep.") at 1112-

13[8]. Accordingly, all Class 1 and Class 2 claims relating to Pulmicort Respules must be dismissed.

Plaintiffs further allege that the purpose of defendants' alleged "scheme" was to provide an illegal kickback to providers (FAMCC ¶ 175) and that defendants' concealed this conduct by instructing providers not to report the price they paid for the drugs at issue (*id.* at ¶ 206.) Again, there is no evidence supporting this allegation in the record. In fact, the undisputed record indicates that Pulmicort Respules is not typically administered by physicians and is rarely even sold to physicians by AstraZeneca. Tab 10, 56.1 Statement ¶ 45 (Ladhani Decl. ¶ 9); 56.1 Statement ¶ 45 (Direct Sales Data, AZ0466414, IMS Data, AZ0716116); Tab 7 (Hartman Dep. at 1130-38 (Plaintiffs' expert admitted that he would be "speculating" as to whether Pulmicort Respules was sold directly to doctors and conceded that, if it were not sold directly to doctors, that would alter his analysis).) Moreover, there is no evidence in the record of any communications whatsoever between AstraZeneca and any provider prescribing or purchasing Pulmicort Respules.

This total failure of evidence supporting the Class 1 and Class 2 claims relating to Pulmicort Respules is not surprising when the only facts in the record relating to Pulmicort Respules are considered. Pulmicort Respules is an inhaled nebulized corticosteroid sold in two strengths for pediatric use in treating asthma; indeed, Pulmicort Respules is approved by the FDA for use in children aged 12 months to 8 years. Tab 8, 56.1 Statement ¶¶ 41, 42, 43 (Product Strategy Plan, Sept. 10, 2003 AZ0682756.) A J-Code was not even assigned to Pulmicort

[8] Although AstraZeneca disputes that Dr. Hartman's "yardstick" analysis is appropriate to determine any liability in this action, plaintiffs cannot possibly pursue any claims relating to Pulmicort Respules when even they concede that no liability exists under their own theory.

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Respules .25 mg strength until January 2002 and Pulmicort Respules .5 mg strength until January 2003, after the filing of this original complaint in this action. Tab 9, 56.1 Statement ¶¶ 48, 49 (Product Strategic Plan, Mar. 17, 2004, AZ0623020); Tab 10, 56.1 Statement ¶ 48, 49 (Ladhani Decl. ¶ 12.) Moreover, AstraZeneca does not market the product for use with the geriatric Medicare Part B population. Tab 10, 56.1 Statement ¶ 50 (Ladhani Decl. ¶ 13.) As such, even assuming Class 1 and Class 2 could establish injury with respect to Pulmicort Respules, which they cannot for the reasons stated above, there is no evidence in the record on which these Classes could establish that AstraZeneca caused any such injury.

In sum, because there is no genuine issue of fact to be tried with respect to the Class 1 and Class 2 claims relating to Pulmicort Respules, summary judgment should be granted with respect to those claims.

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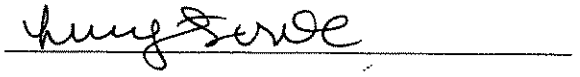
CONCLUSION

For the reasons set forth in the Memorandum of Law in Support of Track 1 Defendants' Joint Motion for Summary Judgment and AstraZeneca's individual memorandum of law, AstraZeneca respectfully requests that the Court grant its motion for summary judgment as to all claims in the FAMCC.

Dated: Boston, Massachusetts
March 15, 2006

Respectfully Submitted,

By: 

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CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was delivered via Federal Express to counsel for plaintiffs on March 15, 2006.


Lucy Fowler